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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/526,106 | 03/15/2000 | Robert F. Balint | PARE.002.01US | 9164 |

20350 7590 09/23/2003

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EXAMINER

EPPERSON, JON D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 09/23/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary*File Copy***Application No.**

09/526,106

Applicant(s)

BALINT ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5,8</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on July 15, 2003 (Paper No. 23).

Priority Claims

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application claims benefit of 60/124,339 (3/15/1999), which claims benefit of 60/135,926 (5/25/1999), which claims benefit of 60/175,968 (1/13/2000) to which priority under 35 U.S.C. 119(e) is claimed. However, the applications upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the claims of this application. In the instant case, none of the applications disclose SEQ ID NO:2 with “a lysine to glutamic acid substitution at position 55” or “a proline to serine substitution at position 62” or a “methionine to threonine substitution at position 182” because SEQ ID NO:2 does not contain a glutamic acid, proline and methionine at positions 55, 62 and 182, respectively (i.e., SEQ ID NO:2 contains a valine, glycine and leucine at positions 55, 62 and 182, respectively). If applicant believes this to be in error, applicant must disclose where in the specification support for these sequences can be found (i.e., indicate, page, paragraph and line numbers for each sequence). Therefore the filing date of the instant application is deemed to be its actual filing date of **March 15, 2000**.

Status of the Claims

3. Claims 1-62 were pending. Applicants cancelled claims 1-62 and added 63-66 in Paper No. 23. Therefore, claims 63-66 are currently pending (see ***Response to Restriction and/or Election of Species*** below)
4. Applicant's election of species (see attached Interview Summary wherein Applicants elected the N-terminal β -lactamase fragment consisting of amino acids 1 to 197 of SEQ ID NO:2 wherein said N-terminal β -lactamase fragment comprises the amino acid substitution (c) a methionine to threonine substitution at position 182; see also ***Response to Restriction and/or Election of Species*** below).
5. Therefore, claims 63-66 are examined on the merits in this action.

Response to Restriction and/or Election of Species

6. As an initial matter, the Examiner withdraws the previous Restriction and Election of Species requirements in view of Applicants cancellation of all original claims (i.e., claims 1-62) in accordance with MPEP § 819.01, "While applicant, as a matter of right, may not shift from claiming one invention to claiming another, the Office is not precluded from permitting a shift. It may do so where the shift results in no additional work or expense, and particularly where the shift reduces work as by simplifying the issues. Ex parte Heritage, Pat. No. 2,375,414 decided January 26, 1944. If the examiner has accepted a shift from claiming one invention to claiming

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another, the case is not abandoned. *Meden v. Curtis*, 1905 C.D.272, 117 O.G. 1795 (Comm'r Pat. 1905)." Here, the Examiner contends that the issues have been simplified because Applicants have restricted their invention to only a functional fragment of SEQ ID NO:2.

7. Applicant's election of species with traverse (see attached interview summary wherein Applicants elected the N-terminal β -lactamase fragment in claim 66) is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).

8. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

9. The information disclosure statement filed November 29, 2002 (Paper No. 5), fails, in part, to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because many of the references lack titles and authors (e.g., numbered C1-C7), necessary elements for consideration. While the other patent and other publications cited therein, and supplied, therewith, have been considered as to the merits, the C1-C7 publications have not. Applicant is advised that the date of any re-submission of these citations contained in this information disclosure statement or the submission of the missing element will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPE § 609 C(1).

Specification

10. The specification is objected to over occurrences of “grant No. _____ awarded by _____” (e.g., page 1, line 14). Applicant must amend the specification to provide the required information at all appropriate locations.
11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant’s cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

12. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Here, figure 2 does not show the first “25” amino acids of SEQ ID NO:2 or in the alternative does not show a lysine, proline and methionine at positions 55, 62 and 182, respectively, as required by claims 63-66 (i.e., assuming that the “H” at position “26” has been mislabeled and should read position “1” to correspond with SEQ ID NO:2), which must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claims Rejections - 35 U.S.C. 112, first paragraph

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 63-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. In new claims 63-66 (introduced in the Preliminary Amendment), the Examiner contends that the specification and claims do not provide support for SEQ ID NO:2 wherein a lysine, proline and methionine are at positions 55, 62 and 182. SEQ ID NO:2 contains a valine, glycine and leucine at positions 55, 62 and 182, respectively. It is noted that an amendment filed along with the filing of an application (as in the present Preliminary Amendment) does not enjoy the status as part of the original disclosure in an application filed under 37 CFR 1.53(b) unless it is specifically referred to in the oath or declaration filed therewith (e.g., see MPEP 608.04b). In the present instance, the oath or declaration fails to specifically refer to the Preliminary Amendment in its "reviewed and understands" clause (which is lacking); nor does the present declaration indicate that a CIP was intended to be filed by applicant.

14. Claims 63-66 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 USC 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January 5, 2001. This is a written description rejection.

With respect to adequate disclosure applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires *representative examples*, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure).

Here, Applicants have not disclosed a single example of SEQ ID NO:2 wherein positions 55, 62 and 182 contain the claimed modifications i.e., (a) a lysine to glutamic acid substitution at position 55, (b) a proline to serine substitution at position 62, and (c) a methionine to threonine substitution at position 182, respectively (see 35 U.S.C. §112, second paragraph rejection below). Consequently, it is the Examiner's position that the lack of guidance in the specification and claims does not provide a "representative" number of examples that would indicate to one of ordinary skill in the art that applicant had possession of a nucleic acid vector molecule of the scope of the claimed invention.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 63-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claims 63-66**, the “substitutions” i.e., (a) a lysine to glutamic acid substitution at position 55, (b) a proline to serine substitution at position 62, and (c) a methionine to threonine substitution at position 182 are vague and indefinite because SEQ ID NO:2 does not contain a lysine, proline and methionine at positions 55, 62, and 182, respectively, as required by claims 63-66. For example SEQ ID NO:2 has a valine, glycine, and leucine at positions 55, 62, and 182, respectively.

Furthermore, if Applicants were to contend that the “positions” of SEQ ID NO: 2 should retain the “numbering” in figure 2 (i.e., His (H) at “position 26” corresponds to “position 1” of SEQ ID NO: 2), which would then show the requisite lysine, proline and methionine at positions 55, 62, and 182, respectively, then the Examiner contends that it is not clear what the first 25 amino acids of SEQ ID NO: 2 are? That is, in order for Applicants to maintain the numbering in Figure 2 an additional 25 amino acids would have to be added to the sequence giving a total sequence length of 288 amino acids (i.e., position 26 cannot simultaneously be both position 1, to give the right sequence length

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i.e., 263 amino acids, and position 26, to give the right numbering i.e., positions 55, 62 and 182 correspond to lysine, proline and methionine, respectively). Applicants are requested to clarify and/or correct. Therefore, claims 63-66 are rejected under 35 U.S.C. 112, second paragraph.

Contact Information

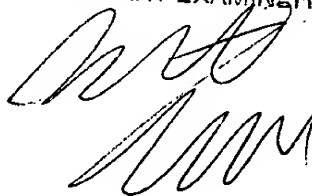
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
September 21, 2003

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Bennett Celsa', is written over the printed name and title.

Interview Summary

Application No.

09/526,106

Applicant(s)

BALINT ET AL.

Examiner

Jon D Epperson

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All participants (applicant, applicant's representative, PTO personnel):

(1) Jon D. Epperson.

(3) _____.

(2) Kenneth E. Jenkins.

(4) _____.

Date of Interview: 18 September 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.

If Yes, brief description: _____.

Claim(s) discussed: 63-66.

Identification of prior art discussed: _____.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicants elected with traverse the B-lactamase fragment in claim 63 consisting of amino acids 1 to 197 of SEQ ID NO:2 wherein said fragment comprises the amino acid substitution (c) a methionine to threonine substitution at position 182.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.